

AMENDMENTS TO THE CLAIMS

Claims 1-2 (Cancelled)

Claim 3 (Currently Amended) A pharmaceutical composition which can be administered orally, consisting essentially of efletirizine as active principle, with at least one fraction which allows immediate release of the efletirizine and at least one fraction which allows prolonged release of the efletirizine, the respective amounts of active principle in the two fractions being the values included on or between the two straight lines defined by the following equations:

$$Y = -0.6786X + 56.675$$

$$Y = -0.6636X + 7.975$$

in which,

Y represents the amount of efletirizine in milligrams (mg) in the immediate-release fraction, and

X represents the amount of efletirizine in milligrams (mg) in the prolonged-release fraction, and

the total amount $X + Y$ being between 10 and 70 mg;

wherein

the two fractions are provided in the form of a two-layer tablet,

wherein

the weight ratio of the amount of active principle in the immediate-release fraction to the amount of active principle in the prolonged-release fraction is between 3 and 0.025,

wherein

the prolonged-release fraction contains 28.4 mg of hydroxypropylmethylcellulosean
excipient of matrixial type, 30 mg dibasic calcium phosphate, 1.7 mg polyvinylpyrrolidone, 0.6
mg colloidal silica and 0.8 mg magnesium stearate,

wherein

the immediate-release fraction contains lactose monohydrate, microcrystalline cellulose, colloidal silica, and magnesium stearate ~~an excipient selected from the group consisting of diluents, binders, disintegrating agents, lubricants and flow enhancers, taste masking agents, flavorings and colorants~~
and wherein

the composition is a single daily dose ~~having bioequivalence to two administrations of 5-25 mg of efletirizine in an immediate release form given 12 hours apart.~~

Claim 4-5 (Cancelled)

Claim 6 (Previously Presented) The composition as claimed in claim 3, wherein the fraction which allows prolonged release of the efletirizine contains less than 5% by weight of basifying agent, weight relative to the total weight of the fraction.

Claim 7 (Cancelled)

Claim 8 (Previously Presented) The composition as claimed in claim 3, wherein the fraction which allows prolonged release of the efletirizine contains 25 mg of efletirizine and the fraction which allows immediate release of the efletirizine contains 10 mg of efletirizine.

Claim 9 (Previously Presented) The composition as claimed in claim 3, wherein the weight ratio of the amount of efletirizine in the immediate-release fraction to the amount of efletirizine in the prolonged-release fraction is between 1.6 and 0.05.

Claim 10 (Currently Amended) The composition as claimed in claim 3, wherein the prolonged-release fraction further ~~contains as excipients dibasic calcium phosphate hydrate, hydroxypropylmethylcellulose, microcrystalline cellulose, colloidal silica and magnesium stearate~~
and wherein

the immediate release fraction contains ~~as excipients~~ 45.6-46.6 mg lactose monohydrate, 26.5-27.5 mg microcrystalline cellulose, 0.4 mg colloidal silica, and 0.8 mg magnesium stearate.

Claims 11-13 (Cancelled)

Claim 14 (Currently Amended) The composition as claimed in claim 31, wherein the prolonged release fraction contains excipient of matricial type ~~is~~ selected from one or more of the group consisting of inert matrices, hydrophilic matrices and lipophilic matrices.

Claim 15 (Currently Amended) The composition as claimed in claim 14, wherein the excipient of matricial type is an inert matrix at a concentration ranging from 20 to 95% relative to the weight of the fraction which allows prolonged release of efletirizine consisting essentially of one or more thermoplastic polymers.

Claim 16 (Currently Amended) The composition as claimed in claim 14, wherein the excipient of matricial type is an inert matrix at a concentration ranging from 20 to 95% relative to the weight of the fraction which allows prolonged release of efletirizine selected from one or more of the group consisting of polyvinyl chloride, polyethylene, copolymers of vinyl acetate and vinyl chloride, poly(methyl methacrylates), polyamides, silicones, ethylcellulose, and polystyrene.

Claim 17 (Currently Amended) The composition as claimed in claim 14, wherein the excipient of matricial type is a hydrophilic matrix at a concentration of 20 to 70% relative to the weight of the fraction which allows prolonged release of efletirizine.

Claim 18 (Currently Amended) The composition as claimed in claim 14, wherein the excipient of matricial type is a hydrophilic matrix comprising one or more gelling excipients at a concentration of 20 to 70% relative to the weight of the fraction which allows prolonged release of efletirizine selected from the group consisting of cellulose derivatives, non-cellulose polysaccharides and acrylic acid polymers.

Claim 19 (Currently Amended) The composition as claimed in claim 141, wherein the excipient of matricial type is a hydrophilic matrix comprising one or more gelling excipients at a concentration of 20 to 70% relative to the weight of the fraction which allows prolonged release of efletirizine selected from the group consisting of hydroxypropylmethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, methylcellulose, galactomannans, guar gum, carob gum, gum arabic, sterculia gum, agar agar, alginates, carbopol 934P and carbopol 974P.

Claim 20 (Currently Amended) The composition as claimed in claim 141, wherein the excipient of matricial type is a lipid matrix at a concentration of 10 to 50% relative to the weight of the fraction which allows prolonged release of efletirizine.

Claim 21 (Currently Amended) The composition as claimed in claim 141, wherein the excipient of matricial type is a lipid matrix at a concentration of 10 to 50% relative to the weight of the fraction which allows prolonged release of efletirizine selected from one or more of the group consisting of glycerides, fatty acids, fatty alcohols, fatty acid esters and waxes.

Claim 22 (Currently Amended) The composition as claimed in claim 141, wherein the excipient of matricial type is a lipid matrix at a concentration of 10 to 50% relative to the weight of the fraction which allows prolonged release of efletirizine selected from one or more of the group consisting of monoglycerides, diglycerides, triglycerides, stearin, palmitin, laurin, myristin, hydrogenated castor or cottonseed oil, precinol, stearic acid, palmitic acid, lauric acid; stearyl alcohol, cetyl alcohol, cetostearyl alcohol, monostearates of propyleneglycol and of sucrose, sucrose distearate, white wax, and sperm whale wax.